REMARKS

Status of Claims

Claims 1-32 were pending in the application and are subject to restriction and/or election requirement.

In view of Applicant's election of Group I in response to the Restriction Requirement, claims 1-25 and 27 are under examination.

In view of the limitation of claim 1 to human and blood, claims 7 and 9 are canceled.

Applicants herewith cancel withdrawn claims 26 and 28-32, and objected to use claim 27.

Regarding the election of species, Applicants appreciate the helpful indication at page 7 of the Office Action that the subject matter corresponding to the elected species is considered fully enabled by the specification. Applicants present this subject matter as new claim 33, and amend all dependent claims to ultimately depend from new claim 33. Thus, it is believed that claims 2-25, 27 and 32 are in condition for allowance.

Applicants now respectfully request rejoinder and examination of additional species.

Claim 34 parallels claim 1, with the additional qualification that "more prominent expression" is characterized by the combination: mean Cy5vsCy3 of greater than 0.62 and Cy3vsCy5 of greater than 0.54, and "less predominant expression" is characterized by the combination: mean Cy5vsCy3 of less than -0.21 and Cy3vsCy5 of less than -0.22, which values can be found in Tables 2 (values for preferred sequences listed in claim 33) and 3 (using all values on Table 3). Claim 35 recites the number of genes or fragments in claim 33. Claim 36 recites the number of genes identified in Table 3. Claims 37 and 38 recite the specific sequences from claim 33 or Table 3, wherein diagnosis is based on at least one of these sequences or fragments being over or under expressed.

Accordingly, claims presented for examination are claims 1-6, 8, 10-25 and 33-38, and cover both over-expression (Table 2) and under-expression (Table 3) as indicators. More importantly, the invention and claims 1 and 34 are not limited to any specific genes or gene fragments, since they are based on the discovery that a variety particular genes are reliably expressed during sepsis, and can be the basis for diagnosis, thus the invention in it's broadest

sense is not limited to the particular sequences listed in Tables 2 or 3, but can involve any gene which is identified as being an indicator of sepsis.

Entry is respectfully requested.

Election/Restriction

Applicant's election with traverse of the invention of Group I, and the particular subcombination of RNAs of SEQ ID NO: 1-7, 9, 10, 78, 79, 81 and 87, in the reply filed on 11/09/2009 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 26 and 28-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/09/2009.

The Examiner notes that no claim is allowed in this Office Action, where claim 10 encompasses non-elected subcombinations of genes. Prior to the allowance of claims that recited non-elected material, any non-elected material that has not been rejoined with the elected subcombination will be required to be removed from the claim.

In response, Applicants now respectfully request rejoinder and examination of additional species, and believes that the allowable invention will correspond in scope to claim 10.

Objection to the Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See for example paras. [0039], [0068], [0081], reference number 24 on page 25. Applicants shall inspect the entirety of the specification to ensure that all instances of browser executable code are removed from the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code.

In response, Applicants have removed all hyperlink from the specification. Applicants have also removed reference to specific claims.

Claim Objections

Claim 1 is objected to because of the following informalities: Part e. of claim 1 recites 'sample A', where the phrase 'sample RNA' is likely intended. Appropriate correction is required.

Applicants thank the Examiner for pointing this out, and have amended claim 1 accordingly.

Claim Rejections – Claim 27 'Use' claim

Claim 27 is rejected under 35 U.S.C. 112, second paragraph. Claim 27 provides for the use of RNA, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 27 is also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101.

Applicants cancel claim 27.

Claim Rejections – 35 USC §112 2nd ¶ Indefiniteness

Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-25 are unclear where it is unclear if the parenthetical terms are required limitations or merely examples of conditions. The Examiner suggests, for example, 'differentiation between non-septic systemic inflammatory response syndrome (SIRS) and sepsis'.

Claim 1 has been amended as suggested by the Examiner.

Claims 1-25 are unclear over recitation of the phrase 'the marker signals', as recited in parts e. and f. of claim 1, because there is not a proper antecedent basis for any 'marker signals' in the claim.

Claim 1 has been amended for clarity.

Claims 2 and 3 are unclear over recitation of the phrase 'the marker signal', as recited in claim 2, because there is not a proper antecedent basis for any 'marker signal' in the claim.

Claim 2 has been amended for antecedent basis.

Claim 3 is unclear over recitation of the phrase 'unchanged gene from the sample', as recited in claim 3, because there is not a proper antecedent basis for any 'unchanged gene' in the claim.

Claim 3 is amended to clarify that it is the expression level, not the gene, that is unchanged.

Claim 6 is unclear over recitation of the phrase 'the clinical treatment', as recited in claim 6, because there is not a proper antecedent basis for any 'clinical treatment' in the claim.

In response, the term "the" has been deleted from claim 6.

Claim 8 is unclear over recitation of the phrase 'are in certain cases subject to lysis', as recited in claim 8, because it is unclear if the claimed method is in fact requiring some lysis, or what conditions are needed to require lysis in the claimed method.

Claim 8 is amended to delete "in certain cases".

Claims 20 and 21 are unclear over recitation of the phrase 'the sample-RNA and the control-RNA and/or enzymatic or chemical derivatives', as recited in claims 20 and 21, because there is not a proper antecedent basis for any 'enzymatic or chemical derivatives' in the claims. The claims may be made clearer in this regard if the unclear phrase is amended to recite 'the sample-RNA and the control-RNA and/or enzymatic or chemical derivatives of the sample-RNA and the control-RNA'.

In response, the language "and/or enzymatic or chemical derivatives" has been removed from these claims.

Claim 22 is unclear over recitation of the phrase 'the immobilized or non- immobilized samples', as recited in claim 22, because there is not a proper antecedent basis for any 'immobilized or non-immobilized samples' in the claim.

In response, the objected to language has been removed.

Claim 23 is unclear over recitation of the phrase 'the DNA sample', as recited in claim 23, because there is not a proper antecedent basis for any 'DNA sample' in the claim.

In response, the term "the" has been removed.

Claims 24 and 25 is unclear over recitation of the phrase 'the individual DNA molecules', as recited in claims 24 and 25, because there is not a proper antecedent basis for any 'individual DNA molecules' in the claims.

In response, the term "the" has been removed.

Claims 24 and 25 is unclear over recitation of the phrase 'the carrier materials', as recited in claims 24 and 25, because there is not a proper antecedent basis for any `carrier materials' in the claims.

In response, the term "the" has been removed.

Withdrawal of the rejections is respectfully requested.

Claim Rejections - 35 USC §112

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph. The Examiner lists the scope for which he sees enablement in the specification, then takes the position that the specification does not reasonably provide enablement for the methods as claimed which broadly encompass diagnostic methods in ***any mammal***, sample RNA from ***any body fluid***, and generically require any gene as having an activity for distinguishing SIRS and sepsis and encompasses gene fragments ***as small as 5 nucleotides***. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In response, Applicants note the guidance provided by the Examiner, present the indicated "enabled" scope as new claim 33, and limit the remaining claims to human, to blood samples, and to 20 nucleotides. Applicants respectfully submit that the claims are now commensurate in scope with the indicated level of enablement.

Double Patenting

Claims 1-9 and 11-25 are ***provisionally*** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 12-29 of copending Application No. 10/551,874. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the conflicting application are

drawn to methods of diagnosing SIRS of sepsis, which would accomplish the same goal as the claims of the instant application in differentiation SIRS from sepsis.

This is a ***provisional*** obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-9 and 11-25 are ***provisionally*** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 11/909,372. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the conflicting application encompass the detection of infections multiple organ failure in a subject, thus encompassing the diagnosis of sepsis in a subject which is the subject matter of the methods of the instant application.

This is a ***provisional*** obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

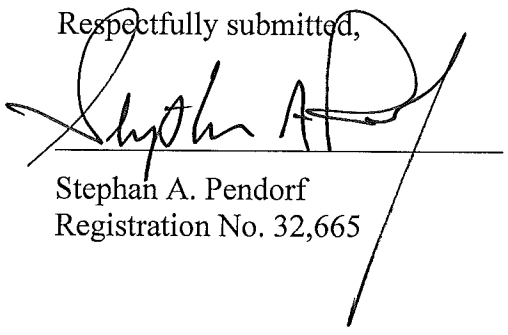
Applicants note the provisional nature of the rejection, and intend to file a Terminal Disclaimer in the event that either rejection is made non-provisional.

Accordingly, Applicants respectfully submit that the application is in condition for allowance.

The Commissioner is hereby authorized to charge any fees which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account Number 16-0877.

Should further issues remain prior to allowance, the Examiner is respectfully requested to contact the undersigned at the indicated telephone number.

Respectfully submitted,



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